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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,186	12/28/2001	Harish Mahalingam	680.0054USU	7732

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EXAMINER	
PATTEN, PATRICIA A	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/034,186	MAHALINGAM ET AL.	
	Examiner	Art Unit	
	Patricia A Patten	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1- 31* is/are pending in the application.

4a) Of the above claim(s) *4, 5 and 15-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-14 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-31 are pending in the application.

Claims 4, 5 and 15-30 were withdrawn from the merits as being directed toward a non-elected species in the Office Action submitted 8/12//03.

Claims 1-3, 6-14 and 31 were examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-9 remain rejected and claims 1-2, 10 – 13 are newly rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a topical lightening agent having melanin synthesis-regulating agent such as coconut water and a melanin uptake-inhibiting agent which is an aqueous extract of perilla, does not

reasonably provide enablement for a composition comprising an effective amount of any melanin synthesis-regulating agent or any melanin uptake-inhibiting agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. Claims 1-2, 6-13 and 31 are further rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Wands factors were recited in the previous Office Action.

It has come to the attention of the Examiner that these claims are not enabled for the entirety of their respective scopes. Further, there is not adequate description in the Specification to support all compounds which have the effect of being a topical lightening agent/melanin synthesis-regulating agent/melanin uptake-inhibiting agent. Although Applicants have provided information in the Specification with regard to effective amounts of substances such as coconut water and aqueous extracts of perilla to perform the functions of the agents as listed in the claims, the Specification does not relay in enough specificity what other compositions have these effects (topical lightening effects, melanin synthesis-regulating and/or melanin uptake-inhibiting effects). Nor has

the Specification provided *effective amounts* for any other agents besides the agents as listed in the Instant claims.

The experimentation needed in order to perform the scope of the claimed invention would involve rigorous trial and error protocols to ascertain all other melanin uptake-inhibiting as well as melanin synthesis-regulating agents, as well as effective amounts of each of these substances. This experimentation would be undue, especially considering that these types of substances are not abundant in nature, and because the Specification has not indicated the structure of all compounds that fit the before-mentioned categories. Therefore, the skilled artisan would need to first *determine* what agents have these effects, and what amount would be efficacious *in-vivo* in order to perform the claimed invention which would entail time consuming, expensive experimentation.

Further, Applicants argue that the Specification teaches that other types of extracts of perilla will be useful for melanin-uptake inhibition, however, have not demonstrated any extract besides the aqueous extract of perilla for such a function. As it was clearly pointed out in the previous Office Action, plant extracts are a priori unpredictable because each respective extraction will produce products with varying pharmaceutical effects. The claims are not drawn to extracts in the specification which have been deemed efficacious, on the contrary, they are broadly drawn to any extract of

perilla. Although the claims are interpreted in light of the specification, limitations from the Specification are not read into the claims. *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, it is deemed that the scope of these claims are not enabled for their breadth for the reasons set forth on the record.

In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

> "Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

Accordingly, in the present instance, the claimed invention encompasses a veritable plethora of possible compounds of diverse structure and type and the use thereof as a melanin synthesis-regulating agent and melanin uptake-inhibiting agent. The inadequate disclosure coupled with a lack of representative examples and the art recognized unpredictability with respect to these types of agent, thus preclude the

making and use of compounds within the scope of the presently claimed invention by the skilled artisan without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 recites 'the method of claim 7'. Claim 7 is actually a composition claim and therefore, this statement lacks antecedent basis in claim 2 rendering claim 31 indefinite. This rejection may be overcome by amending claim 31 to recite 'the composition' rather than 'the method'. This claim was examined on the merits as if it were drawn to 'the composition of claim 7'.

Correction is necessary.

Claim Rejections - 35 USC § 102

Claims 1-3 and 13 remain rejected under 35 U.S.C. 102(b) as anticipated by International Product Alert (IPA)(1994).

Applicant's principal argument in rebuttal to this rejection is the new limitation in claim 1 which reads 'wherein the composition is applied to the skin'. However, this claim is a composition claim. The intended use of the composition, in this case 'to apply to the skin' does not materially change the composition and therefore does not hold any patentable weight. Applicant is asked to review In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). "When the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated" (MPEP 2100 pp. 2113).

Further, although the composition was in a liquid form as disclosed by Product Alert, the liquid form of the composition does not preclude its use on the skin. Therefore, this rejection stands.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 10-13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over IPA (1994).

Again, Applicants primary argument is that the composition is to be used on the skin (same reasoning as set forth in the Arguments against the rejection made under 35 USC 102(b) *supra*). To reiterate, the intended use of the composition does not hold any patentable weight because the intended use, in the instant case does not materially change the composition. Therefore, these claims remain obvious over IPA for the reasons of record.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A Patten whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0968. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia A Patten
Examiner
Art Unit 1654

03/01/04

PATRICIA PATTEN
PATENT EXAMINER